

Remarks

Reconsideration and allowance of this application, as amended, are respectfully requested.

Applicants first note that an executed New Power of Attorney and Change of Correspondence Address form is being submitted concurrently with this Amendment. A corresponding executed Assignment was filed with the U.S. Patent and Trademark Office ("USPTO") on March 1, 2011.

Turning to the instant Amendment, the written description portion of the specification and claims 1-35 have been amended. Claims 1-35 and 45-72 remain pending in the application, with claims 45-72 withdrawn from consideration as being directed to a constructively non-elected invention. Claims 1, 27, 45, 47, and 72 are independent. The rejections are respectfully submitted to be obviated in view of the amendments and remarks presented herein. No new matter has been introduced through the foregoing amendments.

The specification has been editorially amended for conformance with 37 CFR § 1.77(c), for consistency, and to correct any informalities. The claims have been amended in general to more fully comply with U.S. practice.

Entry of each of the amendments is respectfully requested.

Applicants respectfully traverse the USPTO's imposition of the restriction with respect to claims 45-72 and the associated withdrawal of claims 45-72 as being directed to a constructively

non-elected invention. Claims 45-72 were added in Applicants' response filed February 22, 2010, to further define the scope of protection sought for the instant invention. Claims 45-72 simply define other embodiments of the invention based on the originally presented claims of this application.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the restriction with respect to claims 45-72, and examination of all of now pending claims 1-35 and 45-72.

35 U.S.C. § 103(a) - Dadson and Lee

Claims 1-4, 6-12, 18, 19, 21-26, 27, 19 [*sic*, "29"], 31, and 34 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,053,003 to Dadson et al. (hereinafter "Dadson") in view of U.S. Patent No. 4,999,885 to Lee.

The Office Action acknowledges that "Dadson does not expressly disclose the holding member configured to engage portions of the first and second tubular line elements" (Office Action page 7). But, the Office Action relies upon Lee to cure the deficiencies of Dadson, and asserts that, "[i]t would have been obvious . . . to modify the package of Dadson with an organizing means, as taught by Lee because such modification would provide the organizing of the tubing package for use in a peritoneal dialysis treatment in the safety mode" (Office Action, page 8).

The rejection of claims 1-4, 6-12, 18, 19, 21-26, 27, 29, 31, and 34 under § 103(a) based on Dadson and Lee is respectfully traversed. For at least the following reasons, the combined disclosures of Dadson and Lee would not have rendered obvious Applicants' claimed invention.

By way of review, instant claim 1 defines "[a] package for use in a peritoneal dialysis treatment" that includes "a line set including a first tubular line element, a second tubular line element, and a junction connected between the first and second tubular line elements." Claim 1 requires, *inter alia*, "a holding member configured to engage portions of the first and second tubular line elements." And, claim 1 requires that "the first tubular line element [extend] in a first curved shape from a first connector at an outer periphery of the first curved shape to the junction" and that "the second tubular line element [extend] in a second curved shape from a second connector at an outer periphery of the second curved shape to the junction." Finally, claim 1 requires that "the junction [be] disposed at an inner periphery of the first curved shape and an inner periphery of the second curved shape, such that no part of the line set extends across another part of the line set." Importantly, see, e.g., instant Figure 1 for a depiction of the package *configuration* associated with the claimed first tubular line element, second tubular line element, junction, and holding member, and specifically, of the required curved shapes of the tubular line elements.

The combined disclosures of Dadson and Lee do not teach all of Applicants' claimed features. Dadson is deficient, of course, for at least the reasons acknowledged in the Office Action.

Furthermore, Dadson simply discloses an apparatus "that includes a tubing set in a 'Y' configuration" (title and abstract). See, e.g., the "Y" configuration of the tubing set depicted in Dadson's Figures 1 and 4.

That is not Applicants' claimed package, which requires in pertinent part that "the first tubular line element [extend] in a first *curved shape* from a first connector at an outer periphery of the first curved shape to the junction" and that "the second tubular line element [extend] in a second *curved shape* from a second connector at an outer periphery of the second curved shape to the junction," so that "the junction [is] disposed at an inner periphery of the first curved shape and an inner periphery of the second curved shape, such that no part of the line set extends across another part of the line set" (emphasis added).

The Office Action relies upon the disclosure of Lee to rectify the deficiencies of Dadson. More specifically, the Office Action relies upon Lee for the disclosure of "a clip" (Office Action page 7). But the disclosure of Lee is deficient as well. Lee is directed to a "Device for Maintaining Orderly Tubing or Wiring." Lee simply discloses a clip having "a pocket 4 which is dimensioned to engage along the length of an elongated body such as

tubing or wiring" (column 3, lines 56-58). See Lee's description of the clip at column 3, line 31, through column 4, line 6, and the depiction of the clip in Figures 1-3.

But, Lee's "clip" does not meet each element of Applicants' claimed "holding member" feature. Claim 1 requires "a holding member configured to engage portions of *the first and second tubular line elements.*"

And, since Lee simply teaches "a clip," the disclosure of Lee most certainly fails to rectify Dadson's shortcomings in terms of failing to meet Applicants' claimed package *configuration*, which requires that "the first tubular line element [extend] in a first curved shape from a first connector at an outer periphery of the first curved shape to the junction" and that "the second tubular line element [extend] in a second curved shape from a second connector at an outer periphery of the second curved shape to the junction," so that "the junction [is] disposed at an inner periphery of the first curved shape and an inner periphery of the second curved shape, such that no part of the line set extends across another part of the line set" (emphasis added).

Thus, the asserted Dadson/Lee combination fails to teach, *inter alia*, the package *configuration* associated with the claimed first tubular line element, second tubular line element, junction, and holding member, and specifically, the required curved shapes of the tubular line elements. Consequently, the combined disclosures

of Dadson and Lee fail to meet each feature of the claimed invention.

Furthermore, there is simply no teaching in Dadson and Lee that would have led one to select the references and combine them, let alone in a way that would result in the invention defined by Applicants' instant claim 1.

More specifically, in view of Dadson's teaching of "a tubing set in a 'Y' configuration," to assert that "[i]t would have been obvious . . . to modify the package of Dadson with an organizing means, as taught by Lee," is illogical. And, using such logic constitutes an *improper* hindsight reconstruction on the part of the examiner. The hindsight reconstruction is *improper* because it depends upon the disclosure of the *instant application*.

Therefore, the combined disclosures of Dadson and Lee would not have rendered obvious the invention defined by instant claim 1. Claims 2-4, 6-12, 18, 19, and 21-26 are allowable because they depend, either directly or indirectly, from claim 1, and for the subject matter recited therein.

Independent method claim 27 is similarly allowable. Claim 27 requires, *inter alia*, the steps of (i) "positioning the line set within the package such that no part of the line set extends across another part of the line set during a sterilization of the package" and (ii) "retaining the positioning of the line set by fixing a holding member to a portion of the first tubular line

element, a portion of the second tubular line element, a portion of the third tubular line element, and the drain bag," so that "the positioning of the line set and the fixing of the holding member [are] configured to substantially eliminate damage to the package or line set by retaining the patient connector at an inner periphery of the line set and preventing any part of the line set from extending across another part of the line set."

Claim 27 is allowable because the asserted Dadson/Lee combination fails to teach either of the above-quoted method steps, or the package configuration that results therefrom. Claims 29, 31, and 34 are allowable because they depend from claim 27, and for the subject matter recited therein.

35 U.S.C. § 103(a)

Since Dadson and Lee are the primary reference and secondary reference, respectively, in each of the following rejections under § 103(a) -- claims 5, 13, 15-17, 20, 30, 32, and 33 as being unpatentable over Dadson in view of Lee and further in view of U.S. Patent No. 5,850,582 to Keilman; claim 14 as being unpatentable over Dadson in view of Lee and further in view of U.S. Patent No. 4,772,497 to Maasola; and claim 35 as being unpatentable over Dadson in view of Lee and further in view of U.S. Patent Pub. No. 2002/0115795 of Shang et al. ("Shang") -- each of these rejections is similarly traversed. The combined disclosures of the cited references would not have rendered obvious any of the

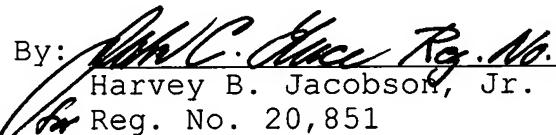
embodiments of Applicants' claimed invention because the disclosures of Keilman, Maasola, and Shang do not rectify any of the above-described deficiencies of Dadson and Lee.

Furthermore, there is simply no teaching in any of Dadson, Lee, Keilman, Maasola, and Shang that would have led one to select the references and combine them, let alone in a way that would result in the various embodiments of the invention defined by any of Applicants' pending claims.

In view of the foregoing, this application is now in condition for allowance. If the examiner believes that an interview might expedite prosecution, the examiner is invited to contact the undersigned.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By: 
Harvey B. Jacobson, Jr.
Reg. No. 20,851

400 Seventh Street, N. W.
Washington, D.C. 20004
Telephone: (202) 638-6666
Date: March 8, 2011